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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,129	03/19/2004	Debasis Bagchi	0VKH-103711	8914

23910 7590 03/08/2007

FLIESLER MEYER LLP
650 CALIFORNIA STREET
14TH FLOOR
SAN FRANCISCO, CA 94108

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,129	BAGCHI ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 7, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-11,18,25,32-34,36-43,51-53,58-60,66,67,72-76,78-85 and 93-104.* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,9-11,18,25,32-34,36-43,51-53,58-60,66,67,72-76,78-85 and 93-104.

Applicants' Amendment filed December 7, 2006 is acknowledged. Claims 2-8, 12-17, 19-24, 26-31, 35, 44-50, 54-57, 61-65, 68-71, 77 and 86-92 are canceled. Claims 1, 9-11, 18, 25, 32-34, 36-43, 51-53, 58-60, 66, 67, 72-76, 78-85 and 93-104 remain under consideration.

Applicants' listing of co-pending and related applications is noted. Provisional obviousness-type double patenting rejections may be applied to S.N. 11/128727, 10/911791, 10/911095, 10/911181, 10/911173, 10/911180 and 11/209429 in due course.

Claims 1, 9-11, 18, 25, 32-34, 36-43, 51-53, 58-60, 66, 67, 72-76, 85 and 93-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 1, 43 and 85 have been amended to recite, "wherein the hydroxycitric acid is bound to calcium and potassium." On page 3, paragraphs [00011] and [00012] of the specification, support is provided for the binding of hydroxycitric acid to one or more metals to form a single, double or triple salt wherein the metals are Li, Na, K, Cs, Fr, Be, Mg, Ca, Sr, Ba or Ra.

Applicants' amendment to claims 1, 43 and 85 results in a mixture of calcium hydroxycitric acid and calcium hydroxycitric acid, not a dual salt.

It is unclear whether Applicants contemplate a mixture of calcium hydroxycitric acid and calcium hydroxycitric acid or a dual salt.

Clarification is required.

In the last Office Action claims 85-104 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-41 of copending Application No. 09/463024. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending application is drawn to compositions comprising a salt of hydroxycitric acid wherein the claimed concentration ranges are encompassed in the present claim language. The open language of the claims allows for the inclusion of additional active agents in the compositions.

Applicants elect to hold this issue in abeyance. The rejection of record on the ground of nonstatutory obviousness-type double patenting is maintained for the reasons of record.

Claims 1-42 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. It was asserted there are no working examples directed to administration of a compound of hydroxycitric acid that is bound to a Group IA or Group IIA metal to form a single, double salt or triple in a model wherein a reduction in serum ghrelin levels is demonstrated.

Applicants argue a working example of hydroxycitric acid bound to calcium and potassium that leads to a reduction in serum ghrelin is given in paragraphs [00034] and [00036].

Applicants' argument is persuasive in that HCA-SX is a potassium/calcium salt of (-) hydroxycitric acid. The rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn.

Applicant's arguments with respect to claims 1-10, 43-52 and 85-94 that were rejected under 35 U.S.C. 102(b) as being anticipated by Clouartre et al., U.S. Patent 6,447,807, and claims 1-77 and 83-104 that were rejected under 35 U.S.C. 103(a) as being unpatentable over Clouartre et al., U.S. Patent 6,447,807, in the last Office Action have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 9-11, 18, 25, 32-34, 36-43, 51-53, 58-60, 66, 67, 72-76, 78-85 and 93-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raju, G., WO 99/03464, in view of Policapelli et al., U.S. Patent 5,612,039, Allen, A., U.S. Patent 5,480,657, Alviar et al., U.S. Patent 6,413,545, and Briggs et al., US 2004/0204472.

Raju teaches hydroxycitric acid compositions that comprise both calcium and potassium for use in the reduction of body weight. See the Abstract. The source of the hydroxycitric acid is found in the rind of the fruits of *Garcinia* species, as, for example, *Garcinia cambogia*. See page 1, lines 21-23, as well as page 3, lines 21-24. As

required by instant claims 11, 18, 25, 53, 58-60, 66, 67, 72, 73, 95-97, a suitable dosage ranges from about 15 to about 3000 mg of hydroxycitric acid. See page 10, lines 18-24. Policappelli teaches the administration of dietary compositions for weight loss comprising *Garcinia cambogia in addition to Gymnema Sylvestre* extract and chromium bound to nicotinate. See claim 8, column 10, where, as required by instant claims 32-34 and 74-76, the administration of the composition is three times daily before a meal. Allen teaches compositions for treatment of weight gain comprising caffeine, as for example, in tea, in addition niacin-bound chrominum. See the Abstract. As required by instant claims 83, 84, 103 and 104, the chromium is present in an amount of approximately 5 mcg to 500 mcg. See lines 1-2, column 9. Alviar teaches compositions for managing body weight comprising effective amounts of *Garcinia cambogia* extract and *Gymnema sylvestre* extract. As required by instant claims 41, 42, 83, 84, 103 and 104, the daily effective amount of Gymnema sylvestre extract is from about 27 to about 293 mg. See column 3, lines 58-62. The open language of the present claims allows for the inclusion of any number of additional active agents.

Briggs teaches antagonists of ghrelin receptors to be effective as weight loss agents. See page 52, Table 3, and claim 8. Decreasing ghrelin levels is deemed to be an inherent property.

See MPEP 2112(1) "[T}he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed.Cir. 1999). Thus,

claiming a new use, new function or unknown property which is, absent factual evidence to the contrary, present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

With respect to claimed dosage ranges of the active agents in the instant compositions and methods of use, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II). The determination of the optimum dosage regimen to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific dosage amounts and dosage regimens are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

In view of the combined references set forth *supra*, one skilled in the art would have been motivated to prepare a composition comprising hydroxycitric acid, optionally bound to calcium and potassium, that is derived from the plant *Garcinia cambogia*,

optionally further comprising gymnemic acid, tea, niacin-bound chromium and caffeine in methods to reduce body weight. Such would have been obvious in the absence of evidence to the contrary because each of the claimed components in Applicants' compositions is disclosed in the prior art for the purpose of reducing body weight.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,9-11,18, 24, 43, 51-53, 58-60, 66, 67, 72, 73, 85 and 93-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhaskaran et al., US 2003/0207942.

Bhaskaran teaches compositions comprising combined potassium-calcium salts of hydroxycitric acid in amounts ranging from about 15 mg to about 3 gm administered up to three times per day. See Example 3, page 4, and page 6, paragraph [0058]. Decreasing ghrelin levels is an inherent property.

See In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) that discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is

a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Applicants' Amendment necessitated the new grounds of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-

0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

March 3, 2007

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER